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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/797,770	02/07/97	BAROFSKY	A 4430-18

EXAMINER

020575
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QM31/0209

ART UNIT	PAPER NUMBER
3738	11

DATE MAILED: 02/09/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on December 28, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24, 36-55, 74, and 76-99 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-24, 36-55, 74, and 76-99 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION-

Oath/Declaration

It is noted that the election with traverse was affirmed in the amendment filed April 6, 1998, but the claims corresponding to the non-elected invention have been canceled.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

> It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Specifically, now that the specification set forth that the present application is a continuation-in-part to two other applications, the declaration needs to be reexecuted to include a reference to the parent applications.

Claim Rejections - 35 USC § 112

Claims 15, 48, 49, and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 15, 48, and 90, line 4 of each claim, "skin,." is a grammatically incorrect manner of ending a sentence and it is unclear where to the Markush ends; the Examiner suggests changing this language to --- and skin.--- in order to overcome this rejection.

With regard to claim 49, there is a sentence fragment on the end of the claim which makes the claim grammatically awkward.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24, 36-55, 74, and 76-99 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014).

Gregory et al is viewed as anticipating the present claims because the soluble elastin used therein is tropoelastin even though it is not called such in the disclosure because the elastin is uncrosslinked and unpolymerized elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al.

Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al on Col. 9, lines 1-26. Furthermore, it is prima fascia obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

Claims 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabaud et al (US 5,223,420) wherein the claimed process of tropoelastin polymerization reads on the Rabaud et al device because tropoelastin is disclosed in the present specification as elastin which is uncrosslinked and unpolymerized. Therefore, since Rabaud et al discloses an unpolymerized and uncrosslinked elastin which is crosslinked or polymerized with fibrin to form an elastin polymer, the Examiner posits that the claimed invention is anticipated thereby; see the whole document, especially the abstract and Col. 2, lines 3-10.

Claims 36-48 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al (US 5,628,785) wherein the claimed process of tropoelastin polymerization reads on the Schwartz et al device because tropoelastin is disclosed in the present specification as elastin which is uncrosslinked and unpolymerized. Therefore, since Schwartz et al discloses an unpolymerized and uncrosslinked elastin which is crosslinked with fibrin to form an elastin polymer, the Examiner posits that the claimed invention is anticipated thereby; see the whole document.

Response to Arguments

Applicant's arguments filed December 28, 1998 have been fully considered but they are not persuasive. Specifically, the Applicant argues that Gregory et al (WO) is not available as a reference because it was invented by the same inventor. However, the Examiner notes that the present inventive entity as well as the descriptive subject matter related to tropoelastin is different in the Gregory et al (WO) and the US Serial No. 08/341,881 cases. Therefore, the Examiner posits that the effective filing date of the present claims is May 31, 1996 or later and that the WO patent is proper prior art due to its earlier publication date and different inventive entity. The Applicant also states that a new declaration will be provided under a separate cover, but no such declaration is of record in the application. For this reason, the rejection relying thereon is hereby maintained.

In response to the traversal of Rabaud et al that tropoelastin is not discloses thereby, the Examiner asserts that tropoelastin is disclosed as unpolymerized and uncrosslinked elastin (see page 1, lines 15-17 of the present specification). Since Rabaud et al discloses unpolymerized and uncrosslinked elastin obtained by animal tissues as in the present specification and then polymerized to form polymerized elastin, the Examiner posits that the unpolymerized or uncrosslinked form of elastin in Rabaud et al is tropoelastin to the extent required by the present claims. Additionally, the Applicant argues that the tropoelastin of the present invention and the elastin of Rabaud et al are different, but he does not specify why this is so. For these reasons, the rejection utilizing Rabaud et al is hereby maintained.

In the traversal of the Schwartz et al rejection, the Applicant argues that Schwartz et al does not disclose a material consisting essentially of tropoelastin. However, according to the present specification, the tropoelastin thereof is crosslinked with another compound to form elastin or polymerized tropoelastin. For this reason, a polymer consisting essentially of tropoelastin could include a crosslinking agent such as fibrin and still be within the scope of the claims. For these reasons, the Examiner posits that the claimed tropoelastin material, both unpolymerized/uncrosslinked and polymerized/crosslinked, are disclosed by and fully met by the uncrosslinked and fibrin crosslinked elastin of Schwartz et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for this Technology Center is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738